REMARKS

These amendments and remarks are being filed in response to the Office Action dated August 22, 2007. For the following reasons this application should be allowed and the case passed to issue.

Claims 1-26 are pending, claims 9 and 15-26 were withdrawn by the Examiner following a restriction requirement. Claim 1 has been amended to include elements of cancelled claims 8 and 10.

I. Priority

The instant application is the national stage of PCT/US03/29536, which in turn claims the benefit of U.S. Provisional Application 60/412,780. The Examiner alleges that the provisional application fails to provide support for nanoparticles that are not cationic such as those embraced by instant claims 1, 3-8 and 10-14 and therefore only grants benefit to the PCT application filing date for these claims.

II. Claims Objections

Claims 1-7 and 10-14 were objected to for reading on non-elected subject matter. Claim 10 was objected to for including an informality. Applicants respectfully submit that the claim amendments obviate the objections and therefore request that the objections be withdrawn.

III. Claim Rejections – 35 U.S.C. § 102

Claims 1, 2, 5-8 and 14 were rejected under 35 U.S.C. 102(b) and (e) as allegedly being anticipated by Felgner U.S. 5,264,618 and claim 1, 8, 11, 13 and 14 were also rejected under 35 U.S.C. § 102(b) and (e) as allegedly being anticipated by Langer et al, U.S. 2020131951.

Applicants respectfully disagree, however in order to expedite prosecution have amended independent claim 1.

Claim 1 recites, "A vaccine delivery system comprising adjuvant and a plurality of nanoparticles comprising nucleic acid encoding an immunogenic antigen, wherein the nanoparticles are coated with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A."

The following is a comparison between the present invention, as claimed and the cited prior art.

Regarding independent claim 1, neither Felgner nor Langer disclose or teach nanoparticles that are **coated** with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A, as required by claim 1.

Anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed Cir. 1987). At a minimum, the cited prior art does not disclose (expressly or inherently) the above recited limitation because both Felgner and Langer fail to disclose nanoparticles that are coated with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A.

As such the prior art references fail to anticipate the claims.

Felgner teaches cationic lipids, but does not teach disclose nanoparticles that are **coated** with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A, as required by claim 1. Langer teaches nanoparticles containing polymer/polynucleotide complexes, the reference does not teach nanoparticles that are **coated** with nucleic acid encoding an

immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A, as required by claim 1.

Therefore, claim 1 is neither anticipated by Felgner or Langer and accordingly the claim should be allowed.

Furthermore, as shown in Fig. 1 and discussed on page 13, line 15 to page 14, line 4, the subject matter of the disclosure as recited in claim 1 has advantages over the prior art,

> "Also, as shown in Fig. 1, the specific IgG titer in sera was enhanced by 14-fold ($p = 0.02$) when mice were immunized with the pDNA-coated nanoparticles with 100 μg cholera toxin, as compared to immunization with the pDNA-coated nanoparticles without CT. The specific total IgG titer from the mice topically immunized with pDNA-coated nanoparticles with 100 μg of cholera toxin was over 300-fold higher than that from mice immunized with 'naked' pDNA alone, strongly indicating an unexpected synergistic effect from the nanoparticles and cholera toxin in inducing antibody production."

Moreover, claims 2-7 and 10-14 depend from and further define the claims over the prior art and therefore should also be allowed.

IV. Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Langer. Claims 1, 3 and 4 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Langer in view of Wolff et al (WO 00/03694). Claim 12 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Langer in view of Deng U.S. 6,667,294.

A. Langer

As discussed above regarding the rejection of claim 1 under 35 U.S.C. § 102(b) and (e) as allegedly being anticipated by Langer, Langer fails to teach or disclose all of the elements of independent claim 1 and therefore is allowable.

Moreover, as shown in Fig. 1 and discussed on page 13, line 15 to page 14, line 4, the subject matter of the disclosure as recited in claim 1 has unexpectedly better results.

> "Also, as shown in Fig. 1, the specific IgG titer in sera was enhanced by 14-fold ($p = 0.02$) when mice were immunized with the pDNA-coated nanoparticles with 100 μg cholera toxin, as compared to immunization with the pDNA-coated nanoparticles without CT. The specific total IgG titer from the mice topically immunized with pDNA-coated nanoparticles with 100 μg of cholera toxin was over 300-fold higher than that from mice immunized with 'naked' pDNA alone, strongly indicating an unexpected synergistic effect from the nanoparticles and cholera toxin in inducing antibody production."

As such it would not be obvious to one having ordinary skill in the art to modify the disclosure of Langer to obtain the nanoparticles as recited in instant claim 1.

Furthermore, claim 3 depends from claim 1 and therefore is also allowable.

In addition, claim 3 is allowable on it's own merits. As an initial matter claim 3 recites in pertinent part, "wherein the nanoparticles are anionic," claim 4 recites in pertinent part "wherein the nanoparticles are neutral." As conceded by the Examiner on page 6 of the Office Action dated August 22, 2007, Langer does not disclose anionic nanoparticles.

Therefore claim 3 is allowable.

B. Langer in view of Wolff

Claims 1, 3 and 4 are rejected 35 U.S.C. § 103(a) as allegedly being unpatentable over Langer in view of Wolff et al (WO 00/03694). The Examiner concedes that Langer does not teach neutral or anionic particles. However relies on Wolff for this alleged disclosure.

As discussed above regarding the rejection of claim 1 under 35 U.S.C. § 102(b) and (e) as allegedly being anticipated by Langer, Langer fails to teach or disclose nanoparticles that are **coated** with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A as required by claim 1.

Moreover, in order to establish a *prima facie* obviousness rejection under 35 U.S.C. § 103(a), all the claim limitations must be taught or suggested by the prior art. *In re Rokya*, 490 F. 2d 981, 180 USPQ 580 (CCPA 1974). Further, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006). At a minimum, the cited prior art does not disclose (expressly or inherently) nanoparticles that are **coated** with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A as required by claim 1.

Wolff fails to cure these deficiencies of Langer, Wolff teaches a process for negatively charging DNA particles. Wolff does not teach or disclose nanoparticles that are **coated** with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A as required by claim 1.

Therefore, neither Langer nor Wolff, either alone or in combination teach all of the elements of claim either expressly or inherently.

Accordingly claim 1 should be allowed.

Moreover, claims 3 and 4 depend from and further define the claim and therefore should also be allowed.

C. Langer in view of Deng

Claim 12 has been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Langer in view of Deng U.S. 6,667,294. The Examiner concedes that Langer does not teach the use of monophosphoryl lipid A as an adjuvant. However relies on Deng for this alleged disclosure.

As discussed above regarding the rejection of claim 1 under 35 U.S.C. § 102(b) and (e) as allegedly being anticipated by Langer, Langer fails to teach or disclose nanoparticles that are coated with nucleic acid encoding an immunogenic polypeptide as required by claim 1.

Deng fails to cure these deficiencies of Langer, Deng teaches a vaccine composition that can be used to protect cats against feline immunodeficiency virus. Deng does not teach or disclose nanoparticles that are **coated** with nucleic acid encoding an immunogenic polypeptide and, wherein the adjuvant is selected from the group consisting of cholera toxin, lipid A, and monophosphoryl lipid A as required by claim 1.

Moreover, as shown in Fig. 1 and discussed on page 13, line 15 to page 14, line 4, the subject matter of the disclosure as recited in claim 1 has unexpectedly better results.

> "Also, as shown in Fig. 1, the specific IgG titer in sera was enhanced by 14-fold ($p = 0.02$) when mice were immunized with the pDNA-coated nanoparticles with 100 μg cholera toxin, as compared to immunization with the pDNA-coated nanoparticles without CT. The specific total IgG titer from the mice topically immunized with pDNA-coated nanoparticles with 100 μg of cholera toxin was over 300-fold higher than that from mice immunized with 'naked' pDNA alone, strongly indicating an unexpected synergistic effect from the nanoparticles and cholera toxin in inducing antibody production."

As such it would not be obvious to one having ordinary skill in the art to modify the disclosure of Langer with that of Deng to obtain the nanoparticles as recited in instant claim 1.

Therefore, neither Langer nor Deng, either alone or in combination teach all of the elements of claim either expressly or inherently.

Accordingly claim 1 should be allowed.

Moreover, claim 12 depend from and further define the claim and therefore should also be allowed.

V. Conclusion

In view of the above amendments and remarks, Applicants submit that this application should be allowed and the case passed to issue. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated to expedite the prosecution of the application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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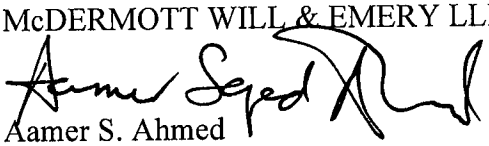

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